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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,253	10/10/2000	Thomas Williams Rademacher	1012-101US	4610
7590		11/28/2003	EXAMINER	
Jonathan Alan Quine		EWOLDT, GERALD R		
PO Box 458		ART UNIT		
Alameda, CA 94501		PAPER NUMBER		
		1644		
DATE MAILED: 11/28/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,253

Applicant(s)

RADEMACHER ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 7-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-23 are pending and being acted upon.
2. Applicant's election with traverse of Group I, Claims 1-6, filed 7/03/03, is acknowledged. Applicant argues, "Applicants submit that the three groups (Group I, Group II and Group III) identified by the Examiner do relate to a single general inventive concept under Rule 13.1 PCT. The stable flipped-out carbohydrate conformation of the derivatised antibodies (and their consequent ability to interact with carbohydrate groups of adjacent molecules) constitutes a special technical feature as required by Rule 13.2 PCT."

These arguments are not found persuasive for the following reasons. As broadly claimed, the antibody of the instant claims (and the method of making said antibody) is not novel and thus fails to constitute a special technical feature. As set forth in U.S. Patent No. 5,191,066, the labeling of carbohydrates in the Fc portion of an antibody by the method of O'Shannessy (1987) results in "conformationally strained antibodies" i.e., the antibodies of the instant claims. Indeed, given the use of acetate buffers that include periodate (O'Shannessy) or triethanolamine (the '066 patent) a certain percentage of the antibodies labeled by either method would be partially denatured and labeled at internal carbohydrate sites, thus teaching the product, and method of making said product, of the instant claims.

Applicant argues, "If at all, linking claim restriction practice should be applied". Applicant is advised that linking claim practice does not apply to claims restricted under Chapter 1800 of the MPEP.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 7-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 1-6 read on the elected invention and are being acted upon.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the recitation of the phrase "The method of claim 1, comprising separating derivatised antibodies which can associate with one another at a site of the immobilised IgG, from those derivatised antibodies which cannot so associate," is vague and indefinite as it is unclear precisely what limitations differentiate an antibody that "associates" from an antibody that does not.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by O'Shannessy et al. (1984).

O'Shannessy et al. teaches a method of producing a derivatised antibody which derivatised antibody is capable of binding to an immobilised IgG, the method comprising: treating a precursor antibody to expose a carbohydrate chain of the precursor antibody from an interstitial site on the surface of the precursor antibody; and chemically derivatising the precursor antibody to prevent the carbohydrate chain from returning to the interstitial site so that the resulting derivatised antibody is capable of binding to the immobilised IgG, said carbohydrate chains further comprising carbohydrate chains which terminate with an N-acetylglucosamine residue (see particularly page 274, column 1). Note that the reference does not specifically teach an antibody comprising carbohydrate chains which terminate with an N-acetylglucosamine residue, however, a certain number of carbohydrate chains in any antibody population would inherently comprise said chains.

The reference clearly anticipates the claimed invention.

8. Claim 1 and 2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,191,066 (of record).


The '066 patent teaches a method of producing a derivatised antibody which derivatised antibody is capable of binding to an immobilised IgG, the method comprising: treating a precursor antibody to expose a carbohydrate chain of the precursor antibody from an interstitial site on the surface of the precursor antibody; and chemically derivatising the precursor antibody to prevent the carbohydrate chain from returning to the interstitial site so that the resulting derivatised antibody is capable of binding to the immobilised IgG, said carbohydrate chains further comprising carbohydrate chains which terminate with an N-acetylglucosamine residue (see particularly Example 1). Note that the reference does not specifically teach an antibody comprising carbohydrate chains which terminate with an N-acetylglucosamine residue, however, a certain number of carbohydrate chains in any antibody population would inherently comprise said chains.

The reference clearly anticipates the claimed invention.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. **Please Note:** inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
November 17, 2003


11/17/03
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER